

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Gary L. Clayman

Serial No.: 08/758,033

Filed: November 27, 1996

For: METHOD AND COMPOSITION FOR
THE DIAGNOSIS AND TREATMENT OF
CANCER

Group Art Unit: 1632

Examiner: Voitach, Joseph T.

Atty. Dkt. No.: INRP:041

Confirmation No.: 5378

CERTIFICATE OF ELECTRONIC SUBMISSION

DATE OF SUBMISSION: November 21, 2006

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

MS AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. § 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be

construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Supplemental Information Disclosure Statement is being filed before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. § 1.114, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b)(4). No fees are believed to be due in connection with the filing of this Supplemental Information Disclosure Statement, however, should any fees under 37 C.F.R. § 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/INRP:041.

Applicant respectfully requests that the listed documents be made of record in the present case.

Respectfully submitted,



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Attorney for Applicant

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Date: November 21, 2006

Form PTO-1449 (modified)		Atty. Docket No. INRP:041	Serial No. 08/758,033
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant Gary L. Clayman	
		Filing Date: November 27, 1996	Group: 1632
U.S. Patent Documents <i>See Page 1-2</i>	Foreign Patent Documents <i>See Page 2-3</i>	Other Art <i>See Page 3-16</i>	

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	2002/0031499	03/14/02	Hedi <i>et al.</i>	424	93.21	12/03/98
	A2	4,740,463	04/26/88	Weinber <i>et al.</i>	435	456	04/13/84
	A3	4,748,022	05/31/88	Busciglio	424	539	12/09/86
	A4	4,822,605	04/18/89	Powell	424	85.2	02/18/86
	A5	4,920,209	04/24/90	Davis <i>et al.</i>	435	235.1	06/04/87
	A6	4,980,289	12/25/90	Temin <i>et al.</i>	435	235.1	04/27/87
	A7	5,055,400	10/08/91	Lo <i>et al.</i>	435	69.1	11/26/86
	A8	5,166,320	11/24/92	Wu <i>et al.</i>	530	395	04/02/90
	A9	5,252,479	10/12/93	Srivastava	435	235.1	11/08/91
	A10	5,328,470	07/12/94	Nabel <i>et al.</i>	604	101.03	07/26/91
	A11	5,362,623	11/08/94	Vogelstein <i>et al.</i>	435	6	03/21/92
	A12	5,496,731	03/05/96	Xu <i>et al.</i>	435	320.1	03/25/93
	A13	5,527,676	06/18/96	Vogelstein <i>et al.</i>	435	6	03/22/93
	A14	5,532,220	07/02/96	Lee <i>et al.</i>	514	44	11/14/94
	A15	5,585,362	12/17/96	Wilson <i>et al.</i>	514	44	06/07/93
	A16	5,747,469	05/05/98	Roth <i>et al.</i>	514	4	04/25/94
	A17	5,891,715	04/06/99	Hedi <i>et al.</i>	435	320.1	11/17/95
	A18	5,932,210	08/03/99	Gregory <i>et al.</i>	424	93.2	10/28/97
	A19	5,994,106	11/30/99	Kovesdi <i>et al.</i>	435	91.4	11/26/96
	A20	6,017,524	01/25/00	Roth <i>et al.</i>	424	93.2	10/13/92
	A21	6,090,566	07/18/00	Vogelstein <i>et al.</i>	435	7.23	06/02/95
	A22	6,143,290	11/07/00	Zhang <i>et al.</i>	424	93.2	04/07/94
	A23	6,410,010	06/25/02	Zhang <i>et al.</i>	424	93.2	10/29/93

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	A24	6,511,847	01/28/03	Zhang <i>et al.</i>	435	320.1	09/21/00
	A25	6,740,320	05/25/04	Zhang <i>et al.</i>	424	93.2	06/02/95
	A26	6,800,617	10/05/04	Vogelstein <i>et al.</i>	514	44	03/22/93

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Language
	B1	EP 0174608	03/19/86	Europe	English
	B2	EP 0351585	01/24/90	Europe	English
	B3	EP 0390323	03/10/90	Europe	English
	B4	EP 0475623	03/18/92	Europe	English
	B5	FR 2688514	03/16/92	France	French
	B6	JP 04-009338	01/14/92	Japan	English Abstract
	B7	WO 90/05180	05/17/90	WIPO	English
	B8	WO 90/10448	09/20/90	WIPO	English
	B9	WO 91/15580	10/17/91	WIPO	English
	B10	WO 93/03769	03/04/93	WIPO	English
	B11	WO 93/19191	09/30/93	WIPO	French (English Abstract)
	B12	WO 93/25224	12/23/93	WIPO	English
	B13	WO 94/06910	03/31/94	WIPO	English
	B14	WO 94/08026	04/14/94	WIPO	English
	B15	WO 94/10323	05/11/94	WIPO	English
	B16	WO 94/18992	09/01/94	WIPO	English
	B17	WO 94/24297	10/27/94	WIPO	French (English Abstract)

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	B18	WO 94/26914	11/24/94	WIPO	French (English Abstract)
	B19	WO 95/02697	01/26/95	WIPO	French (English Abstract)
	B20	WO 95/11301	04/27/95	WIPO	English
	B21	WO 95/11984	05/04/95	WIPO	English
	B22	WO 95/12660	05/11/95	WIPO	English
	B23	WO 95/14101	05/26/95	WIPO	French (English Abstract)
	B24	WO 95/14102	05/26/95	WIPO	French (English Abstract)
	B25	WO 95/23867	09/08/95	WIPO	French (English Abstract)
	B26	WO 95/28948	11/02/95	WIPO	English
	B27	WO 95/30002	11/09/95	WIPO	English

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C60	Anderson, "Human Gene Therapy," <i>Nature</i> , 392:25-30, April 30, 1998.
	C61	Bacchetti, <i>et al.</i> , "Inhibition of Cell Proliferation by and Adenovirus Vector Expressing the Human Wild Type p53 Protein," <i>International Journal of Oncology</i> , 3:781-788, 1993.
	C62	Baker <i>et al.</i> , "Chromosome 17 Deletions and p53 Gene Mutations in Colorectal Carinomas," <i>Science</i> , 244:217-221, April 1989.
	C63	Baker <i>et al.</i> , "p53 Gene Mutations Occur in Combination with 17p Allelic Deletions as Late Events in Colorectal Tumorigenesis," <i>Cancer Research</i> , 50:7717-7722, December 1990.
	C64	Bargonetti <i>et al.</i> , "Wild-type but not mutant p53 immunopurified proteins bind to sequences adjacent to the SV40 origin of replication," <i>Cell</i> , 65:1083-1091, 1991.
	C65	Baum <i>et al.</i> , "The impact of gene therapy on dentistry," <i>Journal of the American Dental Association</i> , 126:179-189, 1995.

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	C66	Berkner, "Development of adenovirus vectors for the expression of heterologous genes," <i>BioTechniques</i> , 6(7):616-629, 1988.
	C67	Berkner, "Expression of heterologous sequences in adenoviral vectors," <i>Current Topics in Microbiology and Immunology</i> , 158:39-66, 1992.
	C68	Bier-Laning <i>et al.</i> , "A phase II multi-center study of AD5CMV-P53 administered intratumorally to patients with recurrent head and neck cancer," <i>ASCO Annual Meeting</i> , abstract No. 1712, 1999.
	C69	Blagosklonny <i>et al.</i> , "In vitro evaluation of a p-53- expressing adenovirus as an anti-cancer drug" <i>Int. J. Cancer</i> , 67:386-392, 1996.
	C70	Bowtell <i>et al.</i> , "Comparison of Expression in Hemopoietic Cells by Retroviral Vectors Carrying Two Genes," <i>Journal of Virology</i> , 62(7):2464-2473, 1988.
	C71	Brachman <i>et al.</i> , "p53 mutation does not correlate with radiosensitivity in 24 head and neck cancer cell lines," <i>Cancer Res.</i> , 53:3667-3669, 1993.
	C72	Brown <i>et al.</i> , "Increased accumulation of p53 protein in cisplatin-resistant ovarian cell lines," <i>Int. J. Cancer</i> , 55:678-684, 1993.
	C73	Brown <i>et al.</i> , "Mutant p53 confers cisplatin-sensitivity to resistant ovarian tumour cells with elevated wild-type p53," <i>Proc. Am. Assoc. Cancer Res.</i> , 34:355, Abstract #2116, 1993.
	C74	Carter <i>et al.</i> , "Adenovirus Containing a Deletion of the Early Region 2A Gene Allows Growth of Adeno-Associated Virus with Decreased Efficiency," <i>Virology</i> , 191:473-476, 1992.
	C75	Casson <i>et al.</i> , "p53 Gene Mutations in Barrett's Epithelium and Esophageal Cancer," <i>Cancer Research</i> , 51:4495-4499, 1991.
	C76	Chang <i>et al.</i> , "Inhibition of intratracheal lung cancer development by systemic delivery of E1A," <i>Oncogene</i> , 13:1405-1412, 1996.
	C77	Chang <i>et al.</i> , "Restoration of the G1 Checkpoint and the Apoptotic Pathway Mediated by Wild-type p53 Sensitizes Squamous Cell Carcinoma of the Head and Neck to Radiotherapy," <i>Arch Otolaryngol Head Neck Surg.</i> , 123:507-512, 1997.
	C78	Chen <i>et al.</i> , "Expression of Wild-Type p53 in Human A673 Cells Suppresses Tumorigenicity but Not Growth Rate," <i>Oncogene</i> , 6:1799-1805, 1991.

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	C79	Cheng <i>et al.</i> , "Suppression of acute lymphoblastic leukemia by the human wild-type p53 gene," <i>Cancer Res.</i> , 52:222-226, 1992.
	C80	Clayman <i>et al.</i> , "Transduction of normal and malignant oral epithelium by an adenovirus vector: the effect of dose and treatment time on transduction efficiency and tissue penetration," <i>Cancer Gene Therapy</i> , 2:105-111, 1995.
	C81	Conroy, "New Gene Therapy Cleared for Use Against Lung Cancer," <i>Biotech Daily</i> , pp. 3-4, September 18, 1992.
	C82	Constenla-Figueiras <i>et al.</i> , "A phase II trial with Ad5CMV-p53 as a single agent in recurrent/refractory SCCHN looking at vector biodistribution and horizontal transmission under normal life conditions," <i>Proc Am Soc Clin Oncol</i> 18: 444a, 1999.
	C83	Crystal, "Transfer of genes to humans: early lessons and obstacles to success" <i>Science</i> , 270:404-409, 1995.
	C84	Culver <i>et al.</i> , "Gene Therapy for Cancer," <i>TIG</i> , 10(5):174-178, 1994.
	C85	Culver, <i>et al.</i> , "In Vivo Gene Transfer with Retroviral Vector-Producer Cells for Treatment of Experimental Brain Tumors," <i>Science</i> , 256:1550-1552, 1992.
	C86	Curiel <i>et al.</i> , "High-efficiency gene transfer mediated by adenovirus coupled to DNA-polylysine complexes," <i>Human Gene Therapy</i> , 3:147-154, 1992.
	C87	Davidson <i>et al.</i> , "A model system for in vivo gene transfer into the central nervous system using adenoviral vector," <i>Nature Genetics</i> , 3:219-223, 1993.
	C88	Debus <i>et al.</i> , <i>J. Cancer Res. Clin. Oncol.</i> , 116(Suppl Part 1):5-162, Abstract #A2.037.09, 1990.
	C89	Donehower, "Tumor suppressor gene p53 and apoptosis," <i>Cancer Bull.</i> , 46(2):161-166, 1994.
	C90	El Rouby <i>et al.</i> , "p53 gene mutation in B-cell chronic lymphocytic leukemia is associated with drug resistance and is independent of MDR1/MDR3 gene expression," <i>Blood</i> , 82(11):3452-3459, 1993.
	C91	El-Deiry <i>et al.</i> , "WAF1, a potential mediator of p53 tumor suppression," <i>Cell</i> , 75:817-825, 1993.
	C92	Eliyahu <i>et al.</i> , "p53 - A potential suppressor gene?" <i>J. Cell. Biochem.</i> , UCLA Symposia on Molecular and Cellular Biology, Abstracts, 19 th Annual Meeting, Supplement 14C:264, #1 030, 1990.

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Exam. Init.	Ref. Des.	Citation
	C93	Eliyahu <i>et al.</i> , "Meth A Fibrosarcoma Cells Express Two Transforming Mutant p53 Species," <i>Oncogene</i> , 3:313-321, 1988.
	C94	Fan <i>et al.</i> , "p53 gene mutations are associated with decreased sensitivity of human lymphoma cells to DNA damaging agents," <i>Cancer Res.</i> , 54(22):5824-5830, 1994.
	C95	Fan <i>et al.</i> , "The role of p53 in cell cycle arrest and apoptosis induced by multiple chemotherapeutic agents in Burkitt's lymphoma cells," <i>Proc. Am. Assoc. Cancer Res.</i> , 35:311, Abstract #1851, 1994.
	C96	Finlay <i>et al.</i> , "The p53 Proto-Oncogene Can Act as a Suppressor of Transformation," <i>Cell</i> , 57:1083-1093, June 1989.
	C97	Fornace, Jr., "Induction by radiation of mammalian genes associated with growth-arrest and apoptosis, and the role for the p53 tumor suppressor in their regulation," <i>Proc. Am. Assoc. Cancer Res.</i> , 35:681-682, 1994.
	C98	Friedmann, "Gene therapy of cancer through restoration of tumor-suppressor functions?" <i>Cancer</i> , 70(6-Suppl):1810-1817, 1992.
	C99	Fritsche <i>et al.</i> , "Induction of nuclear accumulation of the tumor-suppressor protein p53 by DNA-damaging agents," <i>Oncogene</i> , 8:307-318, 1993.
	C100	Fujiwara <i>et al.</i> , "Induction of chemosensitivity in human lung cancer cells <i>in vivo</i> by adenovirus-mediated transfer of the wild-type p53 gene," <i>Cancer Res.</i> , 54:2287-2291, 1994.
	C101	Gebhardt <i>et al.</i> , "A Tumor Suppressor Proto-Oncogene p53 Can Block Progression Through the Cell Cycle," Association of American Physicians, American Society for Clinical Investigation, American Federation for Clinical Research, Subspecialty Meetings, Sheraton Washington Hotel, Washington, DC, May 6, 1990, pg. 447A, Abstract.
	C102	Gjerset <i>et al.</i> , "Dominant effect of transduced wild-type p53 over endogenous mutant p53 in sensitizing tumor cells to therapy," <i>Proceedings of the Am. Assoc. Can. Res.</i> , 36:21, 1995. (Abstract 123)
	C103	Gomez-Foix, <i>et al.</i> , "Adenovirus-Mediated Transfer of the Muscle Glycogen Phosphorylase Gene into Hepatocytes Confers Altered Regulation of Glycogen Metabolism," <i>The Journal of Biological Chemistry</i> , 267(35):25129-25134, 1992.
	C104	Gomez-Manzano, <i>et al.</i> , "Adenovirus-mediated transfer of the p53 gene produces rapid and generalized death of human glioma cells via apoptosis" <i>Cancer Research</i> , 56:694-699, 1996.

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	C105	Gomez-Navarro <i>et al.</i> , "Gene Therapy for Cancer," <i>European Journal of Cancer</i> , 35:867-885, 1999.
	C106	Goodwin <i>et al.</i> , "Randomized phase II study of intratumoral injection of two dosing schedules using a replication-deficient adenovirus carrying the p53 gene (AD5CMV-p53) in patients with recurrent/refractory head and neck cancer meeting," <i>ASCO Annual Meeting</i> , abstract No. 1717, 1999.
	C107	Goyette <i>et al.</i> , "Progression of Colorectal Cancer is Associated with Multiple Tumor Suppressor Gene Defects but Inhibition of Tumorigenicity is Accomplished by Correction of Any Single Defect via Chromosome Transfer," <i>Molecular and Cellular Biology</i> , 12(3):1387-1395, 1992.
	C108	Graham and Prevec, "Manipulation of Adenovirus Vectors," <i>In: Methods in Molecular Biology: Gene Transfer and Expression Protocols</i> , E.J. Murray (ed.), The Humana Press, Inc., Vol. 7, Chapter 11, pp. 109-128, 1991.
	C109	Green, "When the Products of Oncogenes and Anti-Oncogenes Meet," <i>Cell</i> , 56:1-3, 1989.
	C110	Gregory, <i>et al.</i> , "Tumor Suppressor of Gene Therapy of Cancer: Adenoviral Mediated Gene Transfer of p53 into Human Tumor Cell Lines," <i>J. Cell. Biochem. Supp.</i> 18a, p. 237, 1994.
	C111	Gridley <i>et al.</i> , "Evaluation of radiation effects against C6 glioma in combination with vaccinia virus-p53 gene therapy," <i>International J. Oncology</i> , 13:1093-1098, 1998.
	C112	Gudkov <i>et al.</i> , "Isolation of genetic suppressor elements, inducing resistance to topoisomerase II-interaction cytotoxic drugs, from human topoisomerase II cDNA," <i>Proc. Natl. Acad. Sci. USA</i> , 90:3231-3235, 1993.
	C113	Gusterson <i>et al.</i> , "Expression of p53 in Premalignant and Malignant Squamous Epithelium," <i>Oncogene</i> , 6:1785-1798, 1991.
	C114	Gutierrez <i>et al.</i> , "Gene Therapy for Cancer," <i>The Lancet</i> , 339:715-721, 1992.
	C115	Hamada <i>et al.</i> , "Adenovirus-mediated transfer of a wild-type p53 gene and induction of apoptosis in cervical cancer," <i>Cancer Res.</i> , 56(13):3047-54, 1996.
	C116	Hamada <i>et al.</i> , "Growth inhibition of human cervical cancer cells with the recombinant adenovirus p53 <i>in vitro</i> ," <i>Gynecologic Oncology</i> , 60:373-379, 1996.

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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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	C117	Harris <i>et al.</i> , "Adenovirus-mediated p53 gene transfer inhibits growth of human tumor cells expressing mutant p53 protein," <i>Cancer Gene Therapy</i> , 2:121-130, 1996.
	C118	Hecht <i>et al.</i> , "Comparison of wildtype and mutated p53 protein expression induced by UV irradiation of cultured cells," <i>FASEB Journal</i> , 8:A667, #3870, 1994.
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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C223	Wilkinson <i>et al.</i> , "Constitutive and enhanced expression from the CMV major IE promoter in a defective adenovirus vector," <i>Nucleic Acids Research</i> , 20(9):2233-2239, 1992.
	C224	Wills and Menzel, "Adenovirus Vectors for Gene Therapy of Cancer," <i>Journal of Cellular Biochemistry</i> , Supp. 17E, p. 204, Abstract #S216, March-April 1993.
	C225	Wills <i>et al.</i> , "Tumor Suppressor Gene Therapy of Cancer: Adenoviral Mediated Gene Transfer of p53 and Retinoblastoma cDNA into Human Tumor Cell Lines," <i>J. Cell. Biochem. Supp.</i> 18c, p. 204, 1994.
	C226	Zagars <i>et al.</i> , "Head and neck tumors" <i>Clinical Oncology A Multidisciplinary Approach</i> 6:230-245; 314-320, 1983.
	C227	Zhang <i>et al.</i> , "High-efficiency gene transfer and high-level expression of wild-type p53 in human lung cancer cells mediated by recombinant adenovirus," <i>Cancer Gene Therapy</i> , 1:5-13, 1994.
	C228	Zhang <i>et al.</i> , "Generation and Identification of Recombinant Adenovirus by Liposome-Mediated Transfection and PCR? Analysis," <i>BioTechniques</i> , 15(5):868-872, 1993.
	C229	Zhu <i>et al.</i> , "Systemic gene expression after intravenous DNA delivery into adult mice," <i>Science</i> , 261:209-211, 1993.

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EXAMINER:**DATE CONSIDERED:**

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